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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,578	07/28/2001	Ruth F. Eden	HT-109US	9243

7590 09/30/2004

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,578

Applicant(s)

EDEN, RUTH F.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendment filed 29 June 2004 has been received. Claims 1-15 are pending.
2. All rejections not reiterated herein below are withdrawn.
3. The text of those US codes not found in the instant office action may be found in a previous office action.

Claim Rejections - 35 USC § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 5 have been amended to recite that the device comprises an enclosure of relatively small volume and shape unrelated to the volume and shape of the suspension container. This amendment is not supported by the specification as originally filed. Nowhere in the specification is there a discussion of the volume and shape of the enclosure as compared to the volume and shape of a container. In the event that support can be found in the specification, it is respectfully requested that the page and line number where such support may be found is cited.

Claim Rejections - 35 USC § 112, second paragraph

6. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 are vague and indefinite because it is unclear how “relatively small” and “relatively large” are defined, therefore, the meets and bounds of the claims cannot be ascertained.

Claim Rejections - 35 USC § 102

7. Claims 1-15 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shi (US 5,998,184) for reasons of record which are reiterated herein below.

Shi discloses a basket bioreactor comprising a cell propagation device for use alone or in combination with any other bioreactor, wherein said device comprises a culture medium vessel and a perforated basket (e.g. enclosure made of a grid material) positioned in the vessel. The screen defines a cell culture zone within the vessel. The basket perforations are sized, e.g., from 50 120 meshes, to provide a substantially free flow of media in the directions indicated by the arrows in FIG. 2. The basket may be made from metal, such as stainless steel, or any synthetic resin suitably resistant to the bioreactor environment. Such resins include certain polyolefins, polycarbonates and the like. The basket may contain a cell supporting material to entrap anchorage independent cells and to immobilize anchorage dependent cells (e.g. antibody material). The basket may have one removable top cover. Alternatively, it may be designed with many covers to provide stacked sub-columns, thereby accommodating the combined use of different supporting materials. Shi teaches that the cell supporting material is any material

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useful to anchor or otherwise immobilize cells cultured in a bioreactor. Representative supporting materials include fibra-cell disks, Cytodex Microcarriers or porous ceramics, sponge, fibers, porous beads, and peptide-coated beads. See column 1, line 60 through column 2, line 16; column 5, line 38 through column 6, line 24. Shi teaches removal of cell from the bioreactor by disconnecting and shaking loose the cultured cells or using cell detachment enzymes. See column 3, lines 39-46.

Response to Arguments

8. Applicant's arguments filed 29 June 2004 have been fully considered but they are not persuasive.

Applicant argues that independent claims 1 and 5 have been amended to emphasize the large difference in size between Applicant's container and Applicants enclosure and the lack of any shape relationship. Applicant argues that this amendment distinguished over the prior art of Shi because Shi discloses a basket that closely fits inside a container and the beads completely fill the basket. Whereas, the instant invention is directed to a container of about 250ml in size and the basket is in the shape of a teabag about 1 ml in size. Applicant also argues that that mesh size and the beads of Shi are much larger than those of instant invention, and that the instant beads need only to partially fill the basket. Applicant further argue that the instant method requires typically 30 minutes to several hours for incubation, whereas the transit time of the Shi device is measured in seconds or a few minutes.

These arguments have been fully considered but are not persuasive. None of the argued features are claimed. Specifically, Claim 1 has been amended to recite that the container has a relatively large volume and the basket has a relatively small volume, however, the container is

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not claimed. Furthermore, the recitation of the volume and shape of the enclosure is vague and does not provide positive limitations to the claimed device. Claim 1 is directed to a device comprising an enclosure (i.e. basket) made of a grid material enclosing beads coated with antibody. The pores of the basket is smaller than the beads to prevent the beads from leaving the basket, but larger than the size of the target microorganisms. Shi discloses such a device.

The argument that the instant invention is directed to a container for about 250 ml in size and that the basket is in the shape of a tea bag about 1 ml in size is not persuasive. These dimensions are not disclosed and claimed.

The argument that the basket of Shi is larger or has larger pores size than those of instant invention is not persuasive. The specific sizes of the basket and beads have not been claimed. The claims are not limited to a basket where the pores of the basket are smaller than the beads and larger than the size of the microorganisms. Shi teaches such a basket.

The argument that the beads of the instant invention need only to partially fill the basket is not persuasive because this feature is not claimed.

The argument regarding the incubation time is not persuasive because the incubation time is not claimed.

The argument directed toward the Japanese patent has been considered but is not on point since this reference was not cited in the statement of the rejection nor has it been made of record by including it on an IDS.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

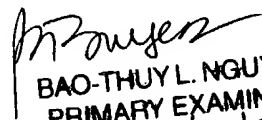
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


BAO-THUY L. NGUYEN
PRIMARY EXAMINER
9/28/04